510(k) SUMMARY

LIQUIDERM™ liquid adhesive bandage

1. Device Name

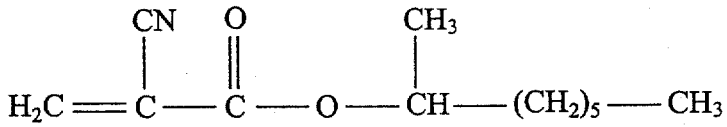
Trade Name:	LIQUIDERM™ liquid adhesive bandage
Common Name:	Liquid adhesive bandage
Classification Name:	Medical Adhesive Bandage, 21 CFR 880.5240
Predicate Device:	BANDAID® brand adhesive bandage (K940536)

2. Device Description

The LIQUIDERM™ liquid adhesive bandage is a sterile, clear, free-flowing liquid containing D&C violet #2 and an antimicrobial preservative system to prevent contamination upon repeated opening of the primary container. The device is packaged in high-density polyethylene multiple-use bottles containing one gram of liquid adhesive and is supplied with 10 individually packaged sterile applicator swabs. The end of each polypropylene swab handle consists of a polyurethane foam sponge tip for device application. The device and applicators are packaged in a cardboard box with a pre-printed display label.

The main component of the LIQUIDERM™ liquid adhesive bandage is monomeric 2-octyl cyanoacrylate. The chemical characteristics of 2-octyl cyanoacrylate are provided below.

Chemical name:	2-octyl cyanoacrylate
CAS registry number:	133978-15-1
Molecular formula:	$C_{12}H_{19}NO_2$
Molecular weight (g/mole):	209
Structural formula:	



3. Intended Use

LIQUIDERM™ liquid adhesive bandage is intended for over-the-counter (OTC) use to cover minor cuts, scrapes, burns, and minor irritations of the skin and help protect them from infection.

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4. Summary of Technological Characteristics

When applied on a wound with the swab applicator, the liquid formulation polymerizes to form a thin, protective film, typically within one minute. Once polymerized, the applied layer of 2-octyl cyanoacrylate has a high degree of adhesion strength and flexibility. The polymer film remains adhered to the tissue surface until the underlying tissue to which it is bonded is spontaneously sloughed through natural re-epithelialization or until mechanically displaced.

5. Summary of Clinical Performance Data

The safety and effectiveness of LIQUIDERM™ liquid adhesive bandage to cover minor cuts and scrapes have been demonstrated through a controlled clinical study. This was a multi-center clinical study of 162 subjects who presented with a minor cut or scrape that had not yet formed a crust or scab. Subjects were randomized to apply either LIQUIDERM™ liquid adhesive bandage or a control bandage (BANDAID® brand adhesive bandage). Subjects enrolled in the study recorded daily observations of bandage performance in a subject diary and were observed by the investigator on day 3, day 6, day 9, day 12, and day 30 for bandage performance and wound healing.

Outcomes of this study show that the LIQUIDERM™ liquid adhesive bandage is safe and effective in covering minor wounds as compared to control. Healing rates for the two devices were shown to be equivalent, and normal healing was observed for all study subjects. Subjects and investigators reported that the directions for use and application method for the LIQUIDERM™ liquid adhesive bandage were effective in allowing subjects to cover their minor wounds in a single application. One application was shown to stay on for an average of 5.6 days, even when exposed daily to water and placed on bending, moving body parts. By comparison, a single application of the control bandage stayed on for an average of 1.5 days and required an average of 5 changes over the study period to provide an appropriate wound covering.

Other significant results of the study were that application of LIQUIDERM™ liquid adhesive bandage was shown to stop minor bleeding for 93% of affected subjects, compared to 46% for control. Also, wound pain was reduced for 35% of subjects applying LIQUIDERM™ liquid adhesive bandage, compared to 15% for control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2001

Mr. W. Thomas Stephens
Manager, Regulatory Affairs
CLOSURE Medical Corporation
5250 Greens Dairy Road
Raleigh, North Carolina 27616

Re: K002338
Trade Name: LIQUIDERM™ Liquid Adhesive Bandage
Regulatory Class: I, Non-Exempt
Product Code: KMF
Dated: November 20, 2000
Received: November 21, 2000

Dear Mr. Stephens:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Philip J. Phillips
Deputy Director for Science and
Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Device Name: LIQUIDERM™ liquid adhesive bandage

Indications For Use:

LIQUIDERM™ liquid adhesive bandage is intended to cover minor cuts, scrapes, burns, and minor irritations of the skin and help protect them from infection.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Philip J Phillips 1-29-01